CLAIMS

What is claimed is:

1. A multi-layer expander member for attachment to a medical catheter comprising:

an outer tensile layer consisting essentially of a biaxially-oriented tubular polymeric film exhibiting relatively high tensile strength and low distensibility; and

an inner bonding layer consisting essentially of a polymeric plastic film adhered to the outer layer, exhibiting relatively high distensibility and having a relatively good adhesive property selected from melt bonding and glue adhesion or a combination thereof.

2. A multi-layer expander member for attachment to a medical catheter comprising in combination:

an outer biaxially-oriented tubular polymeric film tensile layer exhibiting relatively high tensile strength and low distensibility selected from materials of the group consisting of high and medium melt temperature copolymers, high melt temperature polyesters, high melt temperature polyethers, medium melt temperature polyethers, and medium melt temperature polyamides; and

an inner polymeric plastic film bonding layer adhered to the outer layer and exhibiting relatively high distensibility and having good adhesion properties selected from the group consisting of melt bonding and glue adhesion or a combination thereof.

3. The multi-layer expander member of claim 2 wherein:

the outer tensile layer further consists essentially of a material selected from the group consisting of ABS (acrylonitrile-butadiene-styrene), ABS/nylon, ABS/polyvinyl chloride (PVC), ABS/polycarbonate and combinations thereof,

acrylonitrile copolymer, polyacrylamide, polyacrylate, polyacrylsulfone, polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyethylene naphthalate (PEN), liquid crystal polymer (LCP), polyester/polycaprolactone polyester/polyadipate, polyetheretherketone (PEEK), polyethersulfone (PES), polyetherimide (PEI), polyetherketone (PEK), polymenthylpentene, polyphenylene ether, polyphenylene sulfide, styrene acrylonitrile (SAN), nylon 6, nylon 6/6, nylon 6/66, nylon 6/9, nylon 6/10, nylon 6/12, nylon 11 and nylon 12; and

wherein the inner bonding layer consists of a material selected from the group consisting of ethylene propylene, ethylene vinylacetate and ethylene vinyl alcohol (EVA), various ionomers, polyethylene type I-IV, polyolefins, polyurethane, polyvinyl chloride, and polysiloxanes (silicones).

4. The multi-layer expander member of claim 2 wherein the material of the inner layer has relatively good melt bond adhesion and has a melting point below that of the outer layer.

5. The multi-layer expander member of claim 3 wherein the material of the inner layer has relatively good melt bond adhesion and has a melting point below that of the outer layer.

6. The multi-layer expander member of claim 2 wherein the inner layer is not coextensive with the inner surface of the outer layer.

7. The multi-layer expander member of claim 5 wherein the inner layer is not coextensive with the inner surface of the outer layer.

8. The multi-layer expander member of claim 1 further comprising a coating of an hydrophilic, lubricious polymer material on the outer surface of the tensile layer.

9. The multi-layer expander member of claim 3 further comprising a coating of an hydrophilic, lubricious polymer material on the outer surface of the tensile layer.

10. The multi-layer expander member of claim 9 wherein the coating of an hydrophilic, lubricious polymer material is selected from the group consisting of polycaprolactam, polyvinylindol, N-vinylpyrrolidone, and hydrogels.

11. The multi-layer expander member of claim 10 wherein the material of the inner layer has relatively good melt bond adhesion and has a melting point below that of the outer layer.

12. The multi-layer expander of claim 1 wherein the outer and inner layers are coaxially layered.

13. The multi-layer expander of claim 3 wherein the outer and inner layers are coaxially layered.

14. The multi-layer expander member of claim 1 wherein the outer film layer comprises polyethylene terephthalate co-polyester or homopolyester exhibiting a burst pressure in excess of seven atmospheres.

15. The multi-layer expander as in claim 2 wherein the inner film layer comprises an amorphous polyester.

16. The expander as in claim 2 wherein the inner layer comprises a polyolefin.

17. The expander as in claim 16 wherein the outer layer is coated with an hydrophilic polymer.

18. The expander as in claim 17 wherein the hydrophilic polymer is polycaprolactam.

19. An expander member for attachment to an intravascular catheter body member comprising:

an outer coating layer of an hydrophilic, lubricious polymer;

a tubular tensile layer of biaxially oriented polyethylene terephthalate carrying the outer coating layer and exhibiting predetermined expansion and burst-type failure characteristics; and

an inner tubular layer of an amorphous polyester plastic material coaxially adhered to the tensile layer.

20. The expander as in claim 19 wherein the predetermined characteristics include radial expansion not exceeding 3-10 percent.

21. The expander as in claim 19 wherein the predetermined burst pressure is in excess of 7 atmospheres pressure.

22. The expander as in claim 19 and further including hot-melt adhesive layers disposed between the tensile and inner layers.

23. A process for forming a multi-layer expander member for attachment to an intravascular catheter body member comprising the steps of:

co-extruding an outer tensile layer consisting essentially of a biaxially-oriented tubular polymeric film exhibiting relatively high tensile strength and low distensibility, with an inner bonding layer consisting essentially of a polymeric plastic film adhered to the outer layer, exhibiting relatively high distensibility and having a relatively good adhesive property selected from melt bonding and glue adhesion or a combination thereof to form a coaxially layered tubular parison;

heating the parison in a model to a predetermined temperature; and

drawing the parison longitudinally and radially expanding same to biaxially orient the material of the tensile layer such that the expander member exhibits a burst strength greater than about seven atmospheres.

24. The method as in claim 23 wherein the material of the tensile layer is selected from the group consisting of ABS (acrylonitrile-butadiene-styrene), ABS/nylon, ABS/polyvinyl chloride (PVC), ABS/polycarbonate and

combinations thereof, acrylonitrile copolymer, polyacrylamide, polyacrylate, polyacrylsulfone, polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyethylene naphthalate (PEN), liquid crystal polymer (LCP), polyester/polycaprolactone polyester/polyadipate, polyetheretherketone (PEEK), polyethersulfone (PES), polyetherimide (PEI), polyetherketone (PEK), polymenthylpentene, polyphenylene ether, polyphenylene sulfide, styrene acrylonitrile (SAN), nylon 6, nylon 6/6, nylon 6/66, nylon 6/9, nylon 6/10, nylon 6/12, nylon 11 and nylon 12, and the polymeric material of the bonding layer is ~~selected~~ from the class consisting of ethylene propylene, ethylene vinylacetate and ethylene vinyl alcohol (EVA), various ionomers, polyethylene type I-IV, polyolefins, polyurethane, polyvinyl chloride, and ~~polysiloxanes~~ (silicones).

25. The method as in claim 23 and further including the step of:

coating the expander member with a hydrophilic, lubricious plastic.

add B17

add B4

add C'

add E'

add F'

add H2

add I'

add J'

add L'

add M'

add 06'